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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,553	11/05/2001	Jan Yngvar Piene	288748.0003	5786

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EXAMINER	
KHARE, DEVESH	
ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/831,553	PIENE ET AL.	
	Examiner	Art Unit	
	Devesh Khare	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 December 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's Amendment and remarks filed on 12/05/03 are acknowledged.

Claims 6,8,9,12 and 13 have been amended. Claims 15-21 have been cancelled. Rejection of claims 1-14 under 35 U.S.C. 112, first paragraph, has been withdrawn. Claims 1-14 are currently pending in this application.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> *The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claims 1-14 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention of record.

The phrase "optionally mixing said first granulate with one or more further components" in claim 1 (iii) is a relative phrase, which renders the claim indefinite. The phrase "optionally mixing said first granulate with one or more further components" is not defined by the claim, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention, specifically in view of the fact that the claims fail to particularly point out the distinct identity of the "potential" further components.

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth in the record.

Rejection Maintained

Rejection of claims 1-14 under 35 U.S.C. 112, second paragraph is maintained for the reasons of record.

Response to Arguments

Applicant's arguments filed on 12/03/03 traversing the rejection of claims 1-14 under 35 U.S.C. 112, second paragraph have been fully considered but they are not persuasive. Applicants argue that "optionally mixing said granulate with one or more further components" is "clear and understandable to one skilled in the art as the identity of potential further components is disclosed throughout the specification of the instant application". Applicant's claims fail to particularly point out such potential further components. The metes and bounds of the potential further components applicant intends can not be readily ascertained and instant claims are seen to be indefinite.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> *(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.*

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Valentine (EP 0192460) in view of Walsdorf et al. (U.S. Patent 4,814,177) of record.

Claims 1 is drawn to a process for the preparation of an orally administrable calcium composition which is comprised of:

Obtaining a particulate calcium compound having a mean particle size in the range 3 to 40 μm, having a crystalline structure and having a surface area of 0.1 to 1.2 m^2/g and producing a first granulate by mixing the said calcium compound with a water soluble diluent and an aqueous solution of a binder in a fluid bed granulation apparatus and further drying the resulting mixture; optionally producing a second granulate by mixing the first granulate with one or more components; and optionally compressing first or second granulate to form tablets.

Further claim limitations include claims which specify the calcium compounds, claims which specify the amount in wt% of calcium in the first or second granulate, claims in which the calcium compound is mixed with isoflavone, the diluent and binder are same material, claims in which the diluent is at least one sweetener, a claim which specify the specific binder. Applicants also claim the particle size distribution of first granulate and claims which specify additional components mixed with the first granulate selected from vitamin B6, vitamin K, vitamin C, vitamin D, isoflavones, inulin and oligofructose and mixtures of two or more thereof.

Valentine teaches processes for making agglomerates and tablets in a tablet forming apparatus (see abstract). Valentine disclosed insoluble metal and mineral hydroxides and carbonates as active ingredients in the agglomerates (see p. 6, lines 18-20). Valentine disclosed a process for making the carbohydrate-based agglomerate

comprising the active ingredients such as insoluble metal and mineral hydroxides and carbonates in tablet form by mixing them with a water-soluble diluent and an aqueous solution of a water soluble binder to produce the first agglomerate or granulate and then mixing lubricant or flavors to produce the second agglomerate or granulate (see p.8, lines 19- 28 through p.9, lines 1-5). Valentine disclosed a water-soluble binder or sweetener selected from the group consisting of maltodextrine and polyvinylpyrollidone on p. 4, lines 15-17. Also see page 20, lines 2-15, wherein the liquid binder solution and carbohydrate particles including maltodextrin, fructose, sucrose and polyvinylpyrollidone are listed in the agglomerates or granulates. "A well known sweetener, used as a binder will still be a sweetener, or sweet" in a composition. It is noted that Valentine does not provide specific disclosures regarding a calcium compound mixed with isoflavones or vitamins, however, Valentine suggest on p. 12, lines 1-10, use of the said process for making vitamin tablets and dietary supplement and nutrient tablets. Furthermore, under Example XIII (process) on p. 29-30, up to 76.6% wt. of calcium carbonate with a particle size of 3-10 μm is disclosed. It is noted that the present invention is directed to a process to produce a calcium tablet with a calcium compound content in excess of 60% by weight (see specification page 2, lines 1-5). Valentine disclosure differs from applicant's invention in that Valentine does not provide an explicit example of a specific surface area of calcium compound, however Valentine does provide motivation to use a process to produce an orally administrable calcium composition with a calcium compound content in excess of 60% by weight (see p. 2, lines 21-24).

Walsdorf et al. teach a calcium citrate tableting composition containing sugar, polyvinylpyrrolidone and calcium carbonate (see abstract) and a method for producing the same (see claims 1-8). Walsdorf et al. disclose the studies of surface area of calcium citrate composition to understand the greater compressible nature of the calcium citrate composition in col. 5, lines 9-27, disclosing the surface area range for the calcium citrate composition between about 0.7 m^2/g and about 2.0 m^2/g. Walsdorf et al. also disclose in Example 16, col.14, the x-ray analysis of calcium citrate to study the compressibility of the calcium citrate. It is noted that Walsdorf et al. does not provide specific disclosures regarding a process for producing a calcium compound composition with calcium content in excess of 47.5 weight percent (see col. 3, lines 40-43).

Therefore, one of ordinary skill in the art would have found the applicants claimed process for the preparation of an orally administrable calcium composition, to have been obvious at the time the invention was made having the above-cited references before him. Since Valentine teaches processes to produce an orally administrable calcium composition with a calcium compound content in excess of 60% by weight especially up to 76.6% wt. of calcium carbonate with a particle size of 3-10 μm and Walsdorf et al. disclose a method for producing a calcium citrate tableting composition containing the surface area range for the calcium citrate composition between about 0.7 m^2/g and about 2.0 m^2/g, one skilled in the art would have a reasonable expectation for success in combining the procedural steps of the patents to obtain an orally administrable calcium composition. The motivation for doing so is provided in the prior art, which

discloses the process to produce an orally administrable calcium composition with a calcium compound content in excess of 60% by weight is desirable for reducing the size of calcium citrate containing tablets, and providing dietary calcium supplementation. The motivation is provided by Valentine, the prior art suggests that the active ingredient (such as calcium carbonate) can be utilized as a direct compression agglomerate from which a chewable tablet can be made which can liquefy in saliva (see page 7, lines 14-18).

Rejection Maintained

Rejection of claims 1-14 under 35 U.S.C. 103(a) is maintained for the reasons of record. Applicant's arguments traversing the rejection of claims 1-14 under 35 U.S.C. 103(a) have been fully considered but they are not persuasive.

Response to Arguments

Applicants argue, "Valentine is silent on the nature of the calcium carbonate that is suitable to be used in the process of the invention". Valentine teaches the use of active ingredients such as calcium carbonate available in micropulverized powder (-325 mesh and less than 44 micron particle size) (page 12, lines 21-27). Furthermore, Valentine discloses that the preferred particle size for the said active ingredients to be in the range of 3 microns to 10 microns (page 21,lines 5-7 and page 29, Example XIII, lines 27-29).

Applicants also argue that "Contrary to Walsdorf, the claimed invention utilizes ultra-clean and non-porous qualities of calcium carbonate." It is noted that applicant are claiming calcium citrate in claim 2. Walsdorf teaches the use of calcium carbonate in the

process of making a tablet (col. 3, 36-38). Walsdorf uses the X-ray analysis data to learn the compressibility of calcium citrate (col. 5,lines 1-9 and col. 14, Example 16). Walsdorf discloses the preferred surface area of the calcium compound to be in the range of 1.0 m^2 /g– 2.0 m^2 /g (col. 5,lines 25-27).

Indeed, the examiner has established a prima facie case of obviousness rendering claims 1-14 rejected under 35 U.S.C. 103(a) by addressing sufficiently all of the limitations set forth in the instant process for the preparation of an orally administrable calcium composition, one skilled in the art would have a reasonable expectation for success in combining the teachings of Valentine and Walsdorf references to accomplish a process for the preparation of a tablet having a calcium compound such as calcium carbonate used as an active ingredient (Valentine) wherein the compressibility of the said compound in terms of particle size and surface area is determined by the X-ray data because these data are useful in the preparation of more soluble and bioavailable calcium composition (Walsdorf). The motivation is provided by Valentine, the prior art suggests that the active ingredient (such as calcium carbonate) can be utilized as a direct compression agglomerate from which a chewable tablet can be made which can liquefy in saliva (see page 7, lines 14-18).

2. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at (571)272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.
Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
April 20,2004

JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600